A-T

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/434,708	11/05/1999	HAMID BAND	B0801/7159(E	4277

7590 06/14/2004

ELIZABETH R PLUMER
WOLF GREENFIELD & SACKS PC
600 ATLANTIC AVE
BOSTON, MA 02210

EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	09/434,708	BAND ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2004 and 12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,9,11 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-3, 9, 11, 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendments and remarks filed 3/18/04 and 4/12/04 have been entered.

2. Claims 1-3, 9, 11, and 50 are pending and being acted upon. **Note**: Claim 50 is under examination only as it recites a pharmaceutical composition comprising an isolated nucleic acid molecule of Claim 1. The "expression product thereof", i.e., a polypeptide, was restricted to Group II in the restriction requirement mailed 10/25/00.

3. In view of Applicant's amendment, only the following rejection remains.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 50 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for,

an isolated nucleic acid molecule consisting of SEQ ID NO:1 or SEQ ID NO:3, or a nucleic acid molecule that differs from said nucleic acid molecules due to the degeneracy of the genetic code,

does not reasonably provide enablement for, a pharmaceutical composition comprising an isolated nucleic acid molecule consisting of SEQ ID NO:1, for the reasons of record as set forth in the paper mailed 4/08/02 and maintained in the paper mailed 10/16/03.

Applicant's arguments, filed 3/18/04, have been fully considered but they are not persuasive. Applicant argues that "Claim 50 was amended to remove the limitation directed to an effective amount of the agent. The amended claim simply covers the product of claim 1 or an expression product thereof, and a pharmaceutically acceptable carrier. The term pharmaceutically

acceptable carrier is defined in the specification on page 31 lines 18-25."

It remains the Examiner's position that the claim is still drawn to "a pharmaceutical composition", as set forth in the first line of the claim. Accordingly, the composition of the claim must be enabled as a pharmaceutical composition as set forth previously. Applicant's argument that the composition comprises only the composition in a pharmaceutically acceptable carrier is not consistent with the wording of the claim.

6. The following are new grounds of rejection.

7. Claims 1-3, 9, 11, and 50 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for,

an isolated nucleic acid molecule consisting of SEQ ID NO:1 or SEQ ID NO:3, or a nucleic acid molecule that differs from said nucleic acid molecules due to the degeneracy of the genetic code,

does not reasonably provide enablement for complements of said nucleic acid molecules.

A reasonable interpretation of "complements" of the nucleic acids of SEQ ID NO:1 or SEQ ID NO:3 would include complements consisting of fragments of said nucleic acids. As set forth previously, fragments of the nucleic acids of the instant claims are not enabled. Briefly, short fragments only a few nucleotides long would be too small to even encode functional polypeptides of any sort and thus, could not be enabled for any use.

Applicant is advised that the recitation of "nucleic acid molecules fully complementary to the nucleic acid molecules of SEQ ID NO:1 or SEQ ID NO:3" would obviate the rejection.

8. Claims 1-3, 9, 11, and 50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that Applicant was in possession of any compliments of SEQ ID NO:1 or SEQ ID NO:3. As set forth above, "complements" encompasses a virtually unlimited number of nucleic acid fragments. It is noted that the specification discloses no such complementary

fragments. Accordingly, one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

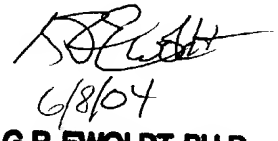
Applicant is advised that the recitation of "nucleic acid molecules fully complementary to the nucleic acid molecules of SEQ ID NO:1 or SEQ ID NO:3" would obviate the rejection.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

11. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600



6/8/04

G.R. EWOLDT, PH.D.
PRIMARY EXAMINER